

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA
EASTERN DIVISION**

THE RELIGIOUS SISTERS OF MERCY,
et al.,

Plaintiffs,

v.

SYLVIA BURWELL, Secretary of the
United States Department of Health
and Human Services, *et al.*,

Defendants.

No. 3:16-cv-386

DEFENDANTS' OPPOSITION
TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Defendants Sylvia Burwell, in her official capacity as Secretary of the United States Department of Health and Human Services, and the United States Department of Health and Human Services, hereby oppose Plaintiffs' motion for preliminary injunction. A memorandum of points and authorities is attached.

Dated: December 7, 2016

Respectfully Submitted,

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney
General

JENNIFER D. RICKETTS
Director, Federal Programs Branch

SHEILA M. LIEBER
Deputy Director, Federal Programs Branch

/s/ Adam Grogg
ADAM GROGG
EMILY BROOKE NESTLER
BAILEY W. HEAPS

Trial Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
20 Massachusetts Ave. NW
Washington, DC 20530
phone: (202) 514-2395
fax: (202) 616-8470
email: adam.a.grogg@usdoj.gov

Counsel for Defendants

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA
EASTERN DIVISION**

THE RELIGIOUS SISTERS OF MERCY,
et al.,

Plaintiffs,

v.

No. 3:16-cv-386

SYLVIA BURWELL, Secretary of the
United States Department of Health
and Human Services, *et al.*,

Defendants.

MEMORANDUM OF POINTS AND AUTHORITIES
IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

TABLE OF CONTENTS

TABLE OF AUTHORITIES	iii
INTRODUCTION	1
BACKGROUND	3
I. Statutory And Regulatory Background.....	3
A. Section 1557 Of The Affordable Care Act	3
B. The Regulation Implementing Section 1557	4
C. Plaintiffs’ Claims Concerning The Rule’s Prohibition On Sex Discrimination	7
1. Nondiscrimination on the basis of sex in the provision of health care services	9
2. Nondiscrimination on the basis of sex in the provision of health insurance coverage	10
D. Administrative And Judicial Enforcement Mechanisms Under Section 1557	12
II. Procedural Background.....	15
STANDARD OF REVIEW	15
ARGUMENT.....	16
I. PLAINTIFFS CANNOT ESTABLISH IRREPARABLE INJURY.....	16
II. PLAINTIFFS ARE UNLIKELY TO SUCCEED BECAUSE THE COURT LACKS JURISDICTION	19
A. Plaintiffs’ Claims Are Not Ripe And Plaintiffs Lack Standing.....	19
B. Section 1557 Requires Plaintiffs To Adhere To Its Specified Mechanisms For Administrative And Judicial Review	22
III. PLAINTIFFS ARE UNLIKELY TO SUCCEED ON THE MERITS	25
A. Plaintiffs’ Statutory Challenges To The Rule Are Not Likely To Succeed.....	25
1. The Rule’s interpretation of Section 1557’s prohibition of sex discrimination as encompassing discrimination based on gender identity should be upheld under <i>Chevron</i>	25
2. Plaintiffs’ remaining statutory claims are meritless.....	32
B. Plaintiffs’ Constitutional Challenges Are Not Likely To Succeed.....	33
1. The Rule Does Not Violate The Spending Clause.....	34
2. Plaintiffs Cannot Succeed On Their First Amendment Claim Because The Rule Does Not Compel Or Curtail Speech.....	36

3. Plaintiffs Have Not Met Their Heavy Burden In Attempting A Facial, Pre-
Enforcement Vagueness Challenge38

IV. THE BALANCE OF THE EQUITIES AND THE PUBLIC INTEREST FAVOR
DENYING PRELIMINARY INJUNCTIVE RELIEF39

CONCLUSION.....40

TABLE OF AUTHORITIES

CASES	PAGE(S)
<i>Avia Sports, Inc. v. Fingerhut Direct Marketing, Inc.</i> , No. 09-cv-1091, 2010 WL 2131007 (D. Minn. May 25, 2010)	40
<i>Bailey v. United States Postal Service</i> , 208 F.3d 652 (8th Cir. 2000)	25
<i>Bakersfield City School District of Kern County v. Boyer</i> , 610 F.2d 621 (9th Cir. 1979)	24
<i>Benning v. Georgia</i> , 391 F.3d 1299 (11th Cir. 2004)	34
<i>Boutilier v. INS</i> , 387 U.S. 118 (1967).....	38
<i>Board of Education of the Highland Local School District v. U.S. Department of Education</i> , No. 2:16-cv-524, 2016 WL 5372349 (S.D. Oh. Sept. 26, 2016)	12, 24, 27
<i>Bowman Transportation, Inc. v. Arkansas-Best Freight Sys., Inc.</i> , 419 U.S. 281 (1974).....	33
<i>Carcaño v. McCrory</i> , No. 1:16-cv-236, 2016 WL 4508192 (M.D.N.C. Aug. 26, 2016)	27
<i>Chemical Manufacturers Association v. Natural Resources Defense Council</i> , 470 U.S. 116 (1985).....	29
<i>Chevron U.S.A. v. Natural Resources Defense Council</i> , 467 U.S. 837 (1984).....	26, 31
<i>City of Arlington v. FCC</i> , 133 S. Ct. 1863 (2013).....	29
<i>City of Los Angeles v. Lyons</i> , 461 U.S. 95 (1983).....	16, 18, 19
<i>Clapper v. Amnesty International</i> , 133 S. Ct. 1138 (2013).....	21
<i>Coit Independence Joint Venture v. FSLIC</i> , 489 U.S. 561 (1989).....	23

<i>Cornish v. Dudas</i> , 540 F. Supp. 2d 61 (D.D.C. 2008)	39
<i>Dataphase Systems, Inc. v. C L Systems, Inc.</i> , 640 F.2d 109 (8th Cir. 1981)	15
<i>Davis v. Monroe County Board of Education</i> , 526 U.S. 629 (1999).....	34
<i>Delta Air Lines v. Export-Import Bank of the United States</i> , 85 F. Supp. 3d 250 (D.D.C. 2015)	21, 22
<i>Elgin v. Department of Treasury</i> , 132 S. Ct. 2126 (2012).....	23, 24, 25
<i>Farkas v. Miller</i> , 151 F.3d 900 (8th Cir. 1998)	39
<i>Farmers Union Agency, Inc. v. Butenhoff</i> , 808 F. Supp. 677 (D. Minn. 1992).....	38
<i>G.G. v. Gloucester County School Board</i> , 822 F.3d 709 (4th Cir. 2016)	27
<i>Giboney v. Empire Store & Ice Co.</i> , 336 U.S. 490 (1949).....	37
<i>Glenn v. Brumby</i> , 663 F.3d 1312 (11th Cir. 2011)	5, 27
<i>Grayned v. City of Rockford</i> , 408 U.S. 104 (1972).....	39
<i>H&R Block Tax Services, LLC v. Acevedo-Lopez</i> , 724 F.3d 1074 (8th Cir. 2014)	19
<i>Harkness v. United States</i> , 727 F.3d 465 (6th Cir. 2013)	22, 23
<i>Hartford-Empire Co. v United States</i> , 323 U.S. 386 (1945).....	40
<i>Hubbard Feeds, Inc. v. Animal Feed Supplement, Inc.</i> , 182 F.3d 598 (8th Cir. 1999)	40

<i>Hunter v. United Parcel Serv., Inc.</i> , 697 F.3d 697 (8th Cir. 2012)	26, 27, 28
<i>Jackson v. Birmingham Board of Education</i> , 544 U.S. 167 (2005).....	34
<i>Jarkesy v. SEC</i> , 803 F.3d 9 (D.C. Cir. 2015).....	23
<i>Jenson v. Eveleth Taconite Co.</i> , 824 F. Supp. 847 (D. Minn. 1993).....	37
<i>Knox v. Service Employees International Union, Local 1000</i> , 132 S. Ct. 2277 (2012).....	36
<i>Liadov v. Mukasey</i> , 518 F.3d 1003 (8th Cir. 2008)	23
<i>Louisiana Environmental Network v. Browner</i> , 87 F.3d 1379 (D.C. Cir. 1996).....	22
<i>Lujan v. Defenders of Wildlife</i> , 504 U.S. 555 (1992).....	20
<i>McCarthy v. Madigan</i> , 503 U.S. 140 (1992).....	23, 24
<i>McDonnell Douglas Corp. v. Green</i> , 411 U.S. 792 (1973).....	18
<i>Miata v. City of Daytona Beach</i> , No. 6:14-cv-1428, 2015 WL 506287 (M.D. Fla. Feb. 6, 2015).....	38
<i>Michigan Association of Homes & Services for Aging, Inc. v. Shalala</i> , 127 F.3d 496 (6th Cir. 1997)	24
<i>NAACP v. Wilmington Med. Ctr., Inc.</i> , 453 F. Supp. 330 (D. Del. 1978).....	24
<i>National Federation of Independent Business v. Sebelius</i> , 132 S. Ct. 2566 (2012).....	35, 36
<i>Natural Resources Defense Council v. EPA</i> , 559 F.3d 561 (D.C. Cir. 2009).....	20

<i>Northwest Austin Municipal Utility District No. One v. Holder</i> , 557 U.S. 193 (2009).....	33
<i>Ohio Forestry Association, Inc. v. Sierra Club</i> , 523 U.S. 726 (1998).....	19
<i>Oncale v. Sundowner Offshore Services, Inc.</i> , 523 U.S. 75 (1998).....	29, 34
<i>Parrish v. Dayton</i> , 761 F.3d 873 (8th Cir. 2014)	20
<i>Pauley v. BethEnergy Mines, Inc.</i> , 501 U.S. 680 (1991).....	29
<i>Pension Benefit Guarantee Corp. v. LTV Corp.</i> , 496 U.S. 633 (1990).....	29
<i>Price Waterhouse v. Hopkins</i> , 490 U.S. 228 (1989).....	<i>passim</i>
<i>R.A.V. v. City of St. Paul</i> , 505 U.S. 377 (1992).....	37
<i>Radtko v. Miscellaneous Drivers & Helpers Union Local No. 638</i> , 867 F. Supp. 2d 1023 (D. Minn. 2012).....	28
<i>Roark & Hardee LP v. City of Austin</i> , 522 F.3d 533 (5th Cir. 2008)	38
<i>Roberts v. Colorado State Board of Agriculture</i> , 998 F.2d 824 (10th Cir. 1993)	39
<i>Rogers v. Windmill Pointe Village Club Association</i> , 967 F.2d 525 (11th Cir. 1992)	39
<i>Rosa v. Park W. Bank & Trust Co.</i> , 214 F.3d 213 (1st Cir. 2000).....	27
<i>Roudachevski v. All-American Care Centers, Inc.</i> , 648 F.3d 701 (8th Cir. 2011)	15
<i>Rumble v. Fairview Health Services</i> , No. 14-cv-2037, 2015 WL 1197415 (D. Minn. Mar. 16, 2015)	28

<i>Rumsfeld v. Forum for Academic & Institutional Rights, Inc.</i> , 547 U.S. 47 (2006).....	37
<i>School District of the City of Saginaw v. U.S. Department of Health, Education, & Welfare</i> , 431 F. Supp. 147 (E.D. Mich. 1977).....	24
<i>Schwenk v. Hartford</i> , 204 F.3d 1187 (9th Cir. 2000)	27, 28
<i>Silver Sage Partners, Ltd. v. City of Desert Hot Springs</i> , 251 F.3d 814 (9th Cir. 2001)	39
<i>Smith v. City of Salem</i> , 378 F.3d 566 (6th Cir. 2004)	27
<i>Sommers v. Budget Marketing, Inc.</i> , 667 F.2d 748 (8th Cir. 1982)	26, 28
<i>South Dakota v. Dole</i> , 483 U.S. 203 (1987).....	34, 35
<i>Spokeo, Inc. v. Robbins</i> , 136 S. Ct. 1540 (2016).....	21
<i>Students & Parents for Privacy v. U.S. Department of Education</i> , No. 16-cv-4945, 2016 WL 6134121 (N.D. Ill. Oct. 18, 2016)	27
<i>Taylor v. Cohen</i> , 405 F.2d 277 (4th Cir. 1968)	24
<i>Texas v. United States</i> , 523 U.S. 296 (1998).....	20
<i>Texas v. United States</i> , No. 7:16-cv-54, 2016 WL 4426495 (N.D. Tex. Aug. 21, 2016)	24, 27
<i>Thunder Basin Coal Co. v. Reich</i> , 510 U.S. 200 (1994).....	23
<i>Trade Around World of PA v. Shalala</i> , 145 F. Supp. 2d 653 (W.D. Pa. 2001).....	24
<i>United States v. Articles of Drug</i> , 825 F.2d 1238 (8th Cir. 1987)	38

<i>United States v. Hayes International Corp.</i> , 415 F.2d 1038 (5th Cir. 1969)	39
<i>University of Texas v. Camenisch</i> , 451 U.S. 390 (1981).....	39
<i>Van Wyhe v. Reisch</i> , 581 F.3d 639 (8th Cir. 2009)	34
<i>Village of Hoffman Estates v. Flipside</i> , 455 U.S. 489 (1982).....	38
<i>Weight Watchers Int’l, Inc. v. Luigino’s, Inc.</i> , 423 F.3d 137 (2d Cir. 2005).....	40
<i>Whitaker v. Kenosha Unified School District No. 1</i> , No. 16-cv-943, 2016 WL 5239829 (E.D. Wis. Sept. 22, 2016)	27
<i>Winter v. Natural Resources Defense Council</i> , 555 U.S. 7 (2008).....	2, 16
<i>Your Home Visiting Nurse Services, Inc. v. Shalala</i> , 525 U.S. 449 (1999).....	29
<i>Zepeda v. INS</i> , 753 F.2d 719 (9th Cir. 1983)	40

STATUTES

5 U.S.C. § 702.....	15
5 U.S.C. § 704.....	15
20 U.S.C. § 1681.....	3, 25, 32
20 U.S.C. § 1682.....	12
20 U.S.C. § 1683.....	12
28 U.S.C. § 1331.....	22
29 U.S.C. § 794.....	3
29 U.S.C. § 794a.....	12
42 U.S.C. § 238n.....	8
42 U.S.C. § 300a-7.....	8, 17
42 U.S.C. § 1316.....	14
42 U.S.C. § 1395cc	14, 24
42 U.S.C. § 18023.....	9, 16, 17
42 U.S.C. § 18116.....	<i>passim</i>
42 U.S.C. § 2000d.....	3
42 U.S.C. § 2000d-1	<i>passim</i>
42 U.S.C. § 2000d-2	<i>passim</i>

42 U.S.C. § 2000bb-1	8
42 U.S.C. § 6101	4
42 U.S.C. § 6104	12
42 U.S.C. § 6105	12
Pub. L. No. 114-223, 130 Stat. 857 (2016)	8
Pub. L. No. 114-113, 129 Stat. 2242 (2015)	8
Pub. L. No. 111-148, 124 Stat. 119 (2010)	3

STATE CODES

N.D. Cent. Code Ann. § 14-02.3-01	17
N.D. Cent. Code Ann. § 14-02.3-04	17

ADMINISTRATIVE MATERIALS

45 C.F.R. § 80.6	12, 13
45 C.F.R. § 80.7	13
45 C.F.R. § 80.8	13
45 C.F.R. § 80.9	14
45 C.F.R. § 80.10	14
45 C.F.R. pt. 92	6
45 C.F.R. § 92.2	<i>passim</i>
45 C.F.R. § 92.4	1, 6, 9
45 C.F.R. § 92.7	7
45 C.F.R. § 92.101	<i>passim</i>
45 C.F.R. § 92.201	7
45 C.F.R. § 92.202	7
45 C.F.R. § 92.203	7
45 C.F.R. § 92.204	7
45 C.F.R. § 92.207	<i>passim</i>
45 C.F.R. § 92.208	7, 10
45 C.F.R. § 92.209	7
45 C.F.R. § 92.302	12, 22
45 C.F.R. § 92.303	7

<i>Nondiscrimination in Health Programs and Activities</i> (Final Rule), 81 Fed. Reg. 31,376 (May 18, 2016)	<i>passim</i>
--	---------------

<i>Nondiscrimination in Health Programs and Activities</i> (Proposed Rule), 80 Fed. Reg. 54,172 (Sept. 8, 2015)	<i>passim</i>
--	---------------

<i>Request for Information Regarding Nondiscrimination in Certain Health Programs or Activities</i> , 78 Fed. Reg. 46,558 (Aug. 1, 2013)	4
---	---

<i>Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws,</i> 76 Fed. Reg. 9,968 (Feb. 23, 2011)	8
---	---

<i>Nondiscrimination on the Basis of Sex in Education Programs and Activities Receiving or Benefiting From Federal Financial Assistance,</i> 40 Fed. Reg. 24,128, 24,142 (June 4, 1975).....	6
---	---

<i>NCD 140.3, Transsexual Surgery,</i> Docket No. A-13-87, 2014 WL 2558402 (HHS DAB May 30, 2014).....	31
---	----

<i>Macy v. Holder,</i> EEOC Appeal No. 0120120821, 2012 WL 1435995 (Apr. 20, 2012).....	5
--	---

MISCELLANEOUS

American Psychiatric Association, <i>Gender Dysphoria</i> (2013)	31
--	----

HUMAN RIGHTS CAMPAIGN, HEALTHCARE EQUALITY INDEX 2014 (2014)	30
--	----

LAMBDA LEGAL, WHEN HEALTH CARE ISN'T CARING: TRANSGENDER AND GENDER- NONCONFORMING PEOPLE (2010)	30
---	----

WPATH, STANDARDS OF CARE FOR THE HEALTH OF TRANSEXUAL, TRANSGENDER, AND GENDER-NONCONFORMING PEOPLE (7th ed. 2012)	31
---	----

INTRODUCTION

Plaintiffs, religiously affiliated health care providers and the State of North Dakota, seek a preliminary injunction to prevent the federal government from enforcing against them two aspects of a regulation that implements Section 1557 of the Affordable Care Act. As relevant here, Section 1557 prohibits sex discrimination in health care programs and activities that receive federal funds, 42 U.S.C. § 18116, and the Department of Health and Human Services (the “Department” or “HHS”) interpreted Section 1557’s prohibition on sex discrimination as encompassing discrimination on the bases of gender identity and termination of pregnancy, *see Nondiscrimination in Health Programs and Activities* (the “Rule”), 81 Fed. Reg. 31,376, 31,388-89 (May 18, 2016) (codified at 45 C.F.R. § 92.4). Plaintiffs’ motion for preliminary injunction should be denied.

First, Plaintiffs have failed to demonstrate irreparable harm. Their allegations of such harm rest on several misunderstandings about the effect and scope of the Rule. Contrary to Plaintiffs’ assertions, the Rule does not require any covered entity to perform, or to provide insurance coverage for, any particular medical services, but rather seeks to ensure that covered entities’ actions are not the product of unlawful discrimination. In addition, Plaintiffs fail to acknowledge the Rule’s built-in protections for medical judgment and religious and conscience-based objections. The Rule does not prevent health care professionals from expressing and exercising their good-faith, nondiscriminatory medical judgment. To the contrary, the Department explicitly acknowledged that “[s]cientific or medical reasons can justify distinctions based on” sex or other grounds on which discrimination is prohibited under the Rule. *Id.* at 31,405. Likewise, the Rule does not override federal statutory protections for religious freedom and conscience—including the Church, Weldon, and Coats amendments, and the Religious Freedom Restoration Act—and it does not displace state laws concerning abortion. Quite the opposite, the Rule recognizes them.

45 C.F.R. § 92.2(b)(2); 81 Fed. Reg. at 31,379 & nn.12-14. Section 1557 and the Rule also incorporate extensive procedures for administrative and judicial review of any allegations of unlawful discrimination. Plaintiffs' claims of irreparable injury ignore the protections that the Rule recognizes and the procedures the Rule provides. Because these protections and procedures cannot be ignored, and the Rule must be read in accordance with its terms, Plaintiffs cannot establish an imminent threat of irreparable injury, which is an essential prerequisite to a preliminary injunction. *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 22 (2008).

For similar reasons, Plaintiffs are unlikely to succeed in this case because this Court lacks jurisdiction. When an allegation of a Section 1557 violation is raised in a specific case before the Department, the covered entity then has an opportunity to rebut the allegations and assert any defenses pursuant to comprehensive procedures for investigating and adjudicating such allegations—procedures that must be exhausted before a finding of unlawful discrimination can be made and federal financial assistance terminated. Until that time, Plaintiffs' injuries are speculative, their claims are unripe, and they lack standing.

Even if Plaintiffs had established irreparable harm and jurisdiction, the Court still should deny Plaintiffs' motion because Plaintiffs have not shown that they are likely to succeed on the merits. Plaintiffs have not demonstrated that Section 1557's prohibition against discrimination on the basis of sex refers solely to discrimination on the basis of biological or chromosomal traits, as opposed to also including discrimination motivated by other "sex-based considerations," *Price Waterhouse v. Hopkins*, 490 U.S. 228, 242 (1989), such as the divergence between a person's gender identity and his or her sex assigned at birth. Courts have generally comprehended the Supreme Court's broad understanding of the statutory concept of sex discrimination as encompassing discrimination based on gender identity, and the policies underlying the Affordable

Care Act weigh in favor of the Department’s interpretation in the health care realm. Viewed through the familiar *Chevron* lens, the Department’s interpretation of Section 1557—set forth after notice-and-comment rulemaking authorized by the statute—as prohibiting discrimination against persons whose gender identity does not match their birth-assigned sex is reasonable and entitled to deference. And Plaintiffs’ remaining claims are meritless for the reasons explained below.

Finally, the public interest and the potential harms to third parties outweigh Plaintiffs’ alleged injuries in this premature case. Plaintiffs cannot show that the balance of the equities is on their side. For all these reasons, Defendants respectfully request that the Court deny Plaintiffs’ motion for preliminary injunction.

BACKGROUND

I. Statutory And Regulatory Background

A. Section 1557 Of The Affordable Care Act

In enacting Section 1557 of the Patient Protection and Affordable Care Act of 2010 (“Affordable Care Act” or “ACA”), Pub. L. No. 111-148, 124 Stat. 119, Congress built on a collection of well-settled federal antidiscrimination laws to guarantee full civil rights protections for federally funded and federally administered programs and activities in the health care sector. For decades, the federal government has promulgated and enforced laws designed to ensure that entities receiving federal funds do not discriminate. For example, Title VI of the Civil Rights Act of 1964 bars the recipients of federal funds from discriminating on the basis of race and national origin. 42 U.S.C. §§ 2000d *et seq.* (“Title VI”). Title IX of the Education Amendments Act of 1972 prohibits entities receiving federal funds from discriminating on the basis of sex in their education programs and activities. 20 U.S.C. §§ 1681 *et seq.* (“Title IX”). Section 504 of the Rehabilitation Act of 1973 prohibits discrimination on the basis of disability in programs receiving federal financial assistance. 29 U.S.C. §§ 794 *et seq.* (“Section 504”). And the Age Discrimination

Act of 1975 prohibits discrimination on the basis of age in programs receiving federal financial assistance. 42 U.S.C. §§ 6101 *et seq.* (the “Age Act”).

Invoking Title VI, Title IX, Section 504, and the Age Act, Section 1557 of the Affordable Care Act applies those four laws’ well-established prohibitions on discrimination—on the bases of race, color, national origin, age, sex, and disability—to federally funded health care programs and activities. Specifically, Section 1557 provides that

[e]xcept as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under [Title VI, Title IX, the Age Act, or Section 504], be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under [Title I of the ACA] (or amendments).

42 U.S.C. § 18116(a).

B. The Regulation Implementing Section 1557

Congress authorized the Secretary of HHS to “promulgate regulations to implement” Section 1557. 42 U.S.C. § 18116(c). Pursuant to that authority, the Department began its rulemaking process in August 2013, when its Office for Civil Rights (“OCR”) published a Request for Information in the Federal Register to solicit information on a number of issues arising under the statute. *See Request for Information Regarding Nondiscrimination in Certain Health Programs or Activities*, 78 Fed. Reg. 46,558 (Aug. 1, 2013). In so doing, the Department emphasized that “Section 1557 builds on a landscape of existing civil rights laws,” noting that before its enactment, “the prohibitions against discrimination on the grounds of race, color, national origin, age and disability in Title VI, the Age Act, and Section 504, respectively,” already applied “to all programs and activities covered by those statutes, including those related to health.” *Id.* at 46,559. As to sex discrimination, because the applicability of Title IX itself is limited “to

education programs and activities of covered entities[.]” the Department acknowledged that “Section 1557 is the first Federal civil rights statute that prohibits sex discrimination in health programs and activities of covered entities.” *Id.*

The Department issued a Notice of Proposed Rulemaking (“NPRM”) in September 2015. 80 Fed. Reg. 54,172 (Sept. 8, 2015). As the Department explained,

One of the central aims of the ACA is to expand access to health care and health coverage for all individuals. Equal access for all individuals without discrimination is essential to achieving this goal. Discrimination in the health care context can often lead to poor and inadequate health care or health insurance or other coverage for individuals and exacerbate existing health disparities in underserved communities. Individuals who have experienced discrimination in the health care context often postpone or do not seek needed health care; individuals who are subject to discrimination are denied opportunities to obtain health care services provided to others, with resulting adverse effects on their health status. Moreover, discrimination in health care can lead to poor and ineffective distribution of health care resources, as needed resources fail to reach many who need them. The result is a marketplace comprised of higher medical costs due to delayed treatment, lost wages, lost productivity, and the misuse of people’s talent and energy.

Id. at 54,194 (footnote omitted); *see id.* at 54,194 n.103 (collecting authorities). The Department’s proposed rule aimed to “help address these issues.” *Id.* at 54,194.

In the NPRM, the Department proposed to define prohibited sex discrimination to include “discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, or gender identity.” *Id.* at 54,176;¹ *see also id.* at 54,172 (noting that of the 303 comments HHS received from individuals

¹ In proposing this definition, the Department took account of federal agencies’ and courts’ conclusions that sex discrimination includes discrimination on the bases of gender identity and termination of pregnancy. *See* 81 Fed. Reg. at 31,384-85 & nn.42-43, 31,387-88 & nn.57-59; *see, e.g.,* Letter from Leon Rodriguez (HHS OCR Director) to Maya Rupert (July 12, 2012) (“Section 1557’s sex discrimination prohibition extends to claims of discrimination based on gender identity”); *Macy v. Holder*, EEOC Appeal No. 0120120821, 2012 WL 1435995, at *7 (Apr. 20, 2012) (Title VII) (“When an employer discriminates against someone because the person is transgender, the employer has engaged in disparate treatment related to the sex of the victim.”); *Glenn v. Brumby*, 663 F.3d 1312, 1317-18 (11th Cir. 2011) (surveying decisions, dating to 2000,

in response to the Request for Information, “239 were personal testimonies from transgender individuals describing their experiences of discrimination in the health care setting”). In addition, while affirming that “a fundamental purpose of the ACA is to ensure that vital health care services are broadly and nondiscriminatorily available to individuals throughout the country,” the Department also sought “to ensure that the rule has the proper scope and appropriately protects sincerely held religious beliefs to the extent that those beliefs conflict with provisions of the regulation.” *Id.* at 54,173. The Department noted that the proposed rule would “not displace . . . protections afforded by provider conscience laws, the Religious Freedom Restoration Act, [and] provisions in the ACA related to abortion services,” *id.* (footnotes omitted); *see id.* at 54,173 nn.5-7, and specifically sought “comment on the extent to which [those] existing protections would provide sufficient safeguards,” *id.* at 54,173.

The Department issued its final rule on May 18, 2016. *See* 81 Fed. Reg. 31,376 (codified at 45 C.F.R. pt. 92). As relevant here, the Rule implements Section 1557’s prohibition against sex discrimination, *see* 45 C.F.R. § 92.101, in “every health program or activity, any part of which receives Federal financial assistance provided or made available by the Department,” *id.* § 92.2(a). The Rule defines sex discrimination as the Department proposed, *i.e.*, to “include[] . . . discrimination on the basis of pregnancy, false pregnancy, termination of pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity.” *Id.* § 92.4; *see* 81 Fed. Reg. at 31,387-90 (responding to comments on this definition and explaining

holding in various contexts that “discrimination against a transgender individual because of her gender-nonconformity is sex discrimination, whether it’s described as being on the basis of sex or gender”); *Nondiscrimination on the Basis of Sex in Education Programs and Activities Receiving or Benefiting From Federal Financial Assistance*, 40 Fed. Reg. 24,128, 24,142 (June 4, 1975) (Title IX) (sex discrimination includes discrimination on the basis of “termination of pregnancy”).

the Department’s rationale).² The Rule specifies that it “does not apply to employment,” except with regard to certain covered entities’ employee health benefit programs. 45 C.F.R. § 92.101(a)(2); *see id.* § 92.208; *see also id.* § 92.207.

Finally, the Rule confirms that “[i]nsofar as the application of any requirement under [the Rule] would violate applicable Federal statutory protections for religious freedom and conscience, such application shall not be required.” *Id.* § 92.2(b)(2); *see* 81 Fed. Reg. at 31,378-81 & nn.12-13, 31,388, 31,435. The Department also clarified that the Rule does not displace “provisions in the ACA related to abortion services.” 81 Fed. Reg. at 31,379; *see id.* at 31,379-80 & n.14, 31,388.

C. Plaintiffs’ Claims Concerning The Rule’s Prohibition On Sex Discrimination

Plaintiffs’ claims are limited to the Rule’s prohibition against sex discrimination (1) in the provision of health care services, and (2) in the provision of health insurance coverage. *See, e.g.,* Pls.’ Mem. in Support of Mot. for Prelim. Inj. (“Pls.’ Br.”) at 6 (Nov. 17, 2016), ECF No. 6. As explained below, Plaintiffs misapprehend the Rule’s scope and what it does (and does not) require. At the outset, three general points deserve emphasis:

First, “[s]cientific or medical reasons can justify distinctions based on” sex under the Rule. 81 Fed. Reg. at 31,405. The Rule does not “seek[] to override . . . medical judgment.” Pls.’ Br. 1.

Second, as with medical judgment, the Rule respects religious views. Because the Rule expressly incorporates “applicable Federal statutory protections for religious freedom and conscience,” 45 C.F.R. § 92.2(b)(2); *see* 81 Fed. Reg. at 31,379 & nn.12-13, no part of the Rule can be applied: so as to require any individual “to perform or assist in the performance of any part

² Plaintiffs’ claims concern the Rule’s definition of sex discrimination as encompassing discrimination on the bases of gender identity and termination of pregnancy only. Most provisions of the Rule are not at issue here, *see, e.g.,* 45 C.F.R. §§ 92.101 (as it pertains to discrimination on the basis of race, color, national origin, age, disability, and sex other than with regard to gender identity and termination of pregnancy), 92.7, 92.201, 92.202, 92.203, 92.204, 92.209, 92.303, and the Rule contains a severability provision, *see id.* § 92.2(c).

of a health service program . . . if his performance or assistance in the performance of such part of such program . . . would be contrary to his religious beliefs or moral convictions,” 42 U.S.C. § 300a-7(d) (“Church Amendment”); so as to “substantially burden a person’s exercise of religion” unless doing so “is the least restrictive means of furthering [a] compelling governmental interest,” *id.* § 2000bb-1(b) (Religious Freedom Restoration Act or “RFRA”); or so as to “discriminat[e]” against “any institutional or individual health care entity . . . on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions,” Pub. L. No. 114-113, Div. H, § 507(d), 129 Stat. 2242, 2649 (2015) (“Weldon Amendment”), *as incorporated*, Pub. L. No. 114-223, Div. C, 130 Stat. 857, 909 (2016).³ Accordingly, the Rule does not “attempt to force doctors to violate their religious beliefs.” Pls.’ Br. 1.

Third, the Rule does not require any covered entity to perform, or to provide insurance coverage for, any particular medical service—whether related to gender transition, termination of pregnancy, or otherwise—but instead simply ensures that health services are provided and covered in nondiscriminatory ways. For example, consistent with the discussion above, the Rule does not state—nor has the Department ever stated—that the Rule requires covered entities to provide or cover abortion services. The Rule specifically incorporates the federal statutory protections for religious and conscience-based objections described above, 45 C.F.R. § 92.2(b)(2), and it does not displace the “provisions in the ACA related to abortion services,” *see* 81 Fed. Reg. at 31,379 & n.14, including the provision that “[n]othing in [the ACA] shall be construed to preempt or

³ *See also* 42 U.S.C. § 238n(a) (“Coats Amendment”); *id.* § 300a-7(b) (Church Amendment). *See generally* *Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws*, 76 Fed. Reg. 9,968, 9,969-70 (Feb. 23, 2011) (providing an overview of the Church, Weldon, and Coats amendments).

otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage[] [or] funding[] . . . [of] abortions,” 42 U.S.C. § 18023(c)(1).

1. Nondiscrimination on the basis of sex in the provision of health care services

The Rule ensures that “an individual shall not, on the basis of . . . sex, . . . be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity to which [the Rule] applies.” 45 C.F.R. § 92.101(a). As noted, the Rule neither requires any provider to perform any particular service nor prevents medical professionals from exercising and expressing their medical judgments in a nondiscriminatory manner. *See, e.g.*, 81 Fed. Reg. at 31,377 (noting that the Rule does not “state that certain practices as a matter of law are ‘always’ or ‘never’ permissible” because “[t]he determination of whether a certain practice is discriminatory typically requires a nuanced analysis that is fact-dependent”).⁴ Indeed, the Rule does not require health care providers “to fundamentally change the nature of their operations.” 81 Fed. Reg. at 31,455. Rather, the Rule simply prevents providers from “deny[ing] or limit[ing] services based on an individual’s sex, without a legitimate nondiscriminatory reason.” *Id.* If a provider establishes that his or her treatment decisions were driven by such a reason—for example, by the nondiscriminatory application of his or her “[s]cientific or medical” judgment to the situation at hand, *id.* at 31,405—there is no violation. The Department has committed that it “*will not second-guess* a covered-entity’s neutral nondiscriminatory application of evidence-based criteria used to make medical necessity . . . determinations.” *Id.* at 31,436-37 (emphasis added).

⁴ No Plaintiff alleges the intent to deny medical services other than those relating to gender transition or termination of pregnancy—services such as treatment for cancer or for a broken bone, for example—to anyone on account of their gender identity or based on them having received services for termination of pregnancy in the past. 45 C.F.R. § 92.4; *see id.* § 92.101. Nor does North Dakota allege the intent to prohibit all medical services for gender transition from being performed at state-run health care facilities. *Cf. Pls.’ Br.* 11.

Likewise, the Rule will not be violated if one of the “Federal statutory protections for religious freedom and conscience” discussed above is applicable. 45 C.F.R. § 92.2(b)(2).

2. Nondiscrimination on the basis of sex in the provision of health insurance coverage

The Rule prohibits specified covered entities, *see id.* § 92.208, from “discriminat[ing] on the basis of . . . sex” in the provision or administration of “health-related insurance or other health-related coverage,” *id.* § 92.207(a).⁵ As the Department has repeatedly explained, the Rule “does not require [health insurance] plans to cover any particular benefit or service”; rather, it prohibits “a covered entity [from having] a coverage policy that operates in a discriminatory manner.” 81 Fed. Reg. at 31,434 (quoting 80 Fed. Reg. at 54,189). No part of the Rule is “intended to determine, or restrict a covered entity from determining, whether a particular health service is medically necessary or otherwise meets applicable coverage requirements in any individual case.” 45 C.F.R. § 92.207(d). Again, the Department “will not second-guess a covered-entity’s neutral nondiscriminatory application of evidence-based criteria used to make medical necessity or coverage determinations.” 81 Fed. Reg. at 31,436-37. Rather, a covered entity must simply “use a nondiscriminatory process to determine whether a particular health service is medically necessary or otherwise meets applicable coverage requirements.” *Id.* at 31,437.

Absent an applicable religious defense, *see* 45 C.F.R. § 92.2(b)(2), the Rule does prohibit covered entities’ health insurance plans from categorically excluding or limiting coverage for “all health services related to gender transition,” *id.* § 92.207(b)(4) (emphasis added). The Department explained that “in singling out the entire category of gender transition services, such an exclusion or limitation systematically denies services and treatments for transgender individuals.” 81 Fed.

⁵ The Rule states that to the extent it “require[s] changes to health insurance or group health plan benefit design,” it becomes effective as to such plans on “the first day of the first plan year . . . beginning on or after January 1, 2017.” 81 Fed. Reg. 31,376.

Reg. at 31,429. Though “[h]istorically, covered entities have justified these blanket exclusions by categorizing all transition-related treatment as cosmetic or experimental[,], . . . such across-the-board categorization is now recognized as outdated and not based on current standards of care.” *Id.* (footnotes omitted); *accord id.* at 31,435. However, the Rule does not “compel insurance coverage for medical transitions,” *e.g.*, Pls.’ Br. 26, or for any other medical services for that matter; instead, the Rule prohibits policies from operating in a discriminatory manner, both in design and implementation. Precluding a categorical exclusion for “all health services related to gender transition,” 45 C.F.R. § 92.207(b)(4), simply means that a covered policy may not automatically deny or limit claims for *all* such services—including not only surgical measures, but also counseling and hormone therapy, for example, *see* 81 Fed. Reg. at 31,434—across the board. And the Department has made clear that it “will evaluate whether a particular exclusion is discriminatory based on the application of longstanding nondiscrimination principles to the facts of the particular plan or coverage.” 81 Fed. Reg. at 31,435.

Significantly, and contrary to Plaintiffs’ repeated allegations, *e.g.*, Pls.’ Br. 31-33, 35-36; Compl. ¶¶ 108-111, by acknowledging that a health insurance policy’s blanket characterization of all transition-related treatment “as cosmetic or experimental” would not be “based on current standards of care,” 81 Fed. Reg. at 31,429, the Department did not purport to establish a national standard of care in this field or regulate what medical advice or particular services health care professionals must provide. To the contrary, the Department specifically “recognize[d] that . . . standards of medical care” “related to gender transition . . . continue to evolve,” *id.* at 31,435, and the Rule expressly disclaims any application that would “determine, or restrict a covered entity from determining, whether a particular health service is medically necessary,” 45 C.F.R. § 92.207(d). In sum, just as the Rule does not mandate that any specific services be covered

generally, it likewise neither “affirmatively require[s] covered entities to cover any . . . procedure or treatment for transition-related care” in particular, nor “preclude[s] a covered entity from applying neutral standards that govern the circumstances in which it will offer coverage to all its enrollees in a nondiscriminatory manner.” 81 Fed. Reg. at 31,429; *see* 45 C.F.R. § 92.207(b)(5).

D. Administrative And Judicial Enforcement Mechanisms Under Section 1557

Congress has prescribed a detailed scheme of administrative and judicial review of alleged violations of Section 1557. HHS regulations and other policies, in turn, govern the agency’s own investigation and enforcement proceedings.

Section 1557 specifies that the “enforcement mechanisms provided for and available under [Title VI, Title IX, Section 504, or the Age Act] shall apply for purposes of violations of” Section 1557. 42 U.S.C. § 18116(a). In each of these statutes, Congress has set forth detailed procedures, based on those first introduced in Title VI in 1964, *see id.* §§ 2000d-1, 2000d-2, for administrative and judicial review of a governmental finding of discrimination and decision to withdraw federal financial assistance, *accord* 20 U.S.C. §§ 1682, 1683 (Title IX); 42 U.S.C. §§ 6104, 6105 (Age Act); 29 U.S.C. § 794a(a)(2) (Section 504). (For the sake of simplicity, the discussion that follows refers to the Title VI statutory provisions only.) The Rule likewise specifies that the procedures set forth in the Department’s Title VI regulations govern proceedings concerning alleged discrimination under Section 1557. 45 C.F.R. § 92.302(a) (citing 45 C.F.R. §§ 80.6-11).⁶

⁶ The Department has stated that, “based on the statutory language, a private right of action and damages for violations of Section 1557 are available to the same extent that such enforcement mechanisms are provided for and available under Title VI, Title IX, Section 504, or the Age Act with respect to recipients of Federal financial assistance.” 81 Fed. Reg. at 31,439; *see* 45 C.F.R. § 92.302(d). If any Section 1557 lawsuit were brought against Plaintiffs by a private litigant, Plaintiffs would “retain[] the ability, of course, to raise as a defense . . . [the] arguments” that they attempt to present here. *Bd. of Educ. of the Highland Local Sch. Dist. v. U.S. Dep’t of Educ.*, No. 2:16-cv-524, 2016 WL 5372349, at *2 (S.D. Ohio Sept. 26, 2016).

Section 1557 investigations are conducted by HHS's Office for Civil Rights. In keeping with Congress's instructions, OCR's goal at every step is to help covered entities achieve "compliance . . . by voluntary means" wherever possible. 42 U.S.C. § 2000d-1; *see, e.g.*, 45 C.F.R. §§ 80.6(a), 80.7(d)(1), 80.8(a), 80.8(d). Indeed, although as of September 2015 OCR was receiving approximately 3,000 civil rights complaints annually, 80 Fed. Reg. at 54,207, in the past fifteen years, only one of OCR's civil rights enforcement actions required resolution, as a last resort, through the termination of federal financial assistance by the Department.

An OCR investigation may be instituted after an OCR compliance review, 45 C.F.R. § 80.7(a), or after OCR receives a complaint asserting potential discrimination, *id.* § 80.7(b). OCR investigations "include, where appropriate, a review of the pertinent practices and policies of the [covered entity], the circumstances under which the possible noncompliance . . . occurred, and other factors relevant to a determination as to whether the" covered entity failed to comply with Section 1557. *Id.* § 80.7(c). If OCR determines, after review of a complaint and any subsequent investigation, that further action is not warranted, OCR will inform both the covered entity and any complainant. *Id.* § 80.7(d)(2). If, on the other hand, an investigation indicates a potential Section 1557 violation, OCR must inform the covered entity and attempt to resolve the matter "by informal means whenever possible." *Id.* § 80.7(d)(1).

If OCR "determine[s] that compliance cannot be secured by voluntary means," 42 U.S.C. § 2000d-1, HHS can either refer the matter to the Department of Justice and recommend that judicial proceedings be brought, *see id.*; 45 C.F.R. § 80.8(a), or HHS can institute administrative proceedings to determine whether to terminate the covered entity's Departmental funding, 42 U.S.C. § 2000d-1; 45 C.F.R. § 80.8(c); *see* 81 Fed. Reg. at 31,439. Such administrative proceedings begin with notice to the covered entity of the relevant charges and the proposed

enforcement action, 45 C.F.R. § 80.9(a), and also provide the covered entity an “opportunity for hearing,” 42 U.S.C. § 2000d-1; *see* 45 C.F.R. § 80.9(a). Hearings are conducted in accordance with the Administrative Procedure Act (“APA”). *See* 45 C.F.R. § 80.9. At the conclusion of a hearing, the hearing officer—an administrative law judge—issues either an initial or recommended decision that is subject to review by the Department’s Civil Rights Reviewing Authority, *id.* § 80.10(a), and by the Secretary, *see id.* § 80.10(e).

Any final decision terminating federal financial assistance under Section 1557 can only operate prospectively, and must include “an express finding on the record . . . of a failure to comply with [a] requirement” under that provision. 42 U.S.C. § 2000d-1. Congress has also provided that “such termination . . . shall be limited to the particular political entity, or part thereof, or other recipient as to whom such a finding has been made and, shall be limited in its effect to the particular program, or part thereof, in which such noncompliance has been so found.” *Id.* In addition, any termination cannot be made effective until thirty days after the Department files “a full written report of the circumstances and the grounds” for the termination “with the committees of the House and Senate having legislative jurisdiction over the program or activity involved.” *Id.*

Finally, in addition to prescribing the administrative proceedings described above, *see id.*, Congress has ensured the opportunity for judicial review of any final decision by the Department terminating federal financial assistance on the basis of noncompliance with Section 1557, *see id.* § 2000d-2. Specifically, judicial review may be had either (1) “as may otherwise be provided by law for similar action taken by [the Department] on other grounds”—*i.e.*, as set forth in the statutory scheme governing the particular federal financial assistance at issue, *id.*; *see, e.g., id.* § 1395cc(h)(1)(A) (providing for judicial review of an HHS decision terminating certain Medicare funding); *id.* § 1316(e)(2)(C) (same, Medicaid); or (2) in the event any such statutory scheme does

not itself provide for judicial review, under the APA, *id.* § 2000d-2; *see* 5 U.S.C. §§ 702, 704. Accordingly, in the unlikely event of a Departmental decision withdrawing financial assistance on the basis of a violation of Section 1557, Plaintiffs could pursue their claims in court at that point.

II. Procedural Background

Plaintiffs filed suit on November 7, 2016. *See* Compl., ECF No. 1. Plaintiffs consist of the State of North Dakota, *see id.* ¶ 9, and the “Non-State Plaintiffs,” which assert religious objections to certain of the Rule’s alleged requirements: the Religious Sisters of Mercy, “a Catholic order of religious sisters,” *id.* ¶ 1, “some of [whom] serve in healthcare facilities,” *id.* ¶ 2; two clinics owned and operated by the Sisters of Mercy, *id.* ¶ 3; Sisters of Mary of the Presentation Health System (“SMP Health System”), “a non-profit Catholic health system,” *id.* ¶ 4; and the University of Mary, “a Roman Catholic Benedictine University,” *id.* ¶ 7. Plaintiffs moved for a preliminary injunction on November 17, 2016. ECF No. 5.

STANDARD OF REVIEW

“A preliminary injunction is an extraordinary remedy and the burden of establishing the propriety of an injunction is on the movant.” *Roudachevski v. All-Am. Care Ctrs., Inc.*, 648 F.3d 701, 705 (8th Cir. 2011). In determining whether to grant Plaintiffs’ motion for preliminary injunction, the Court “should consider four factors”: the “threat of irreparable harm” to Plaintiffs, the “probability” that Plaintiffs “will succeed on the merits,” the balance between the threat of irreparable harm that Plaintiffs allege “and the injury that granting the injunction will inflict on other parties,” and “the public interest.” *Id.* (citing *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 114 (8th Cir. 1981) (en banc)).

ARGUMENT

I. PLAINTIFFS CANNOT ESTABLISH IRREPARABLE INJURY

A preliminary injunction cannot be entered based on a mere “possibility” of irreparable harm; rather, a plaintiff must “demonstrate that irreparable injury is *likely* in the absence of an injunction.” *Winter*, 555 U.S. at 22. The threat of irreparable injury must be “real,” “substantial,” and “immediate.” *City of L.A. v. Lyons*, 461 U.S. 95, 111 (1983).

Plaintiffs’ alleged injuries are none of these things. The crux of Plaintiffs’ theory of irreparable injury is that Plaintiffs face the possibility of losing their Departmental funding, and that to avoid a federal fund cutoff, the Rule “coerc[es] [the Non-State Plaintiffs] to provide harmful medical procedures or objectionable insurance coverage in direct violation of their faith,” Pls.’ Br. 38, and “strips North Dakota of its right to enforce its own laws in its healthcare programs and workplaces,” “invalidat[es] religious accommodations for state employees,” *id.* at 39, and “requires North Dakota to provide gender transition procedures, even when its doctors believe such procedures are harmful,” *id.* at 11. In fact, the Rule does none of these things. Under the Rule, “[s]cientific or medical reasons can justify distinctions based on” sex, 81 Fed. Reg. at 31,405; “religious freedom and conscience” are protected, 45 C.F.R. § 92.2(b)(2); and state laws “regarding the prohibition of . . . coverage[] [or] funding . . . [of] abortions,” 42 U.S.C. § 18023(c), are not displaced, *see* 81 Fed. Reg. at 31,379 & n.14. Plaintiffs are conspicuously silent when it comes to these built-in protections. Their silence is telling. Particularly once those protections are considered—which, under the Rule, they must be, *see* 45 C.F.R. § 92.2(b)(2); 81 Fed. Reg. at 31,379—it becomes clear that the injuries Plaintiffs allege are not “*likely*,” *Winter*, 555 U.S. at 22.

For example, Plaintiffs argue at length that the Rule violates RFRA, Pls.’ Br. 21-29, but their argument makes no sense given that the Rule explicitly disavows any application that would violate that statute, *see* 45 C.F.R. § 92.2(b)(2); 81 Fed. Reg. at 31,379 & n.13. The Rule also does

not prevent covered entities from accommodating their employees' religious beliefs: excusing an objecting provider and allowing a non-objecting provider to perform a particular service does not violate the Rule. The Rule expressly incorporates protections for providers' religious freedom and conscience, 45 C.F.R. § 92.2(b)(2), including that "[n]o individual shall be required to perform or assist in the performance of any part of a health service program . . . if his performance or assistance in the performance of such part of such program . . . would be contrary to his religious beliefs or moral convictions," 42 U.S.C. § 300a-7(d). Plaintiff Sisters of Mercy (for example) fails to take these protections into account in alleging that the Rule will require the Sisters "to offer medical services that violate their . . . religious beliefs when they serve in healthcare organizations that are covered entities under the Rule." Compl. ¶ 57.

Plaintiffs' claims about the Rule's purported requirements concerning abortion are likewise unfounded. As noted above, the Rule does not state that it requires covered entities to provide or cover abortion services, it incorporates federal statutory protections for religious freedom and conscience, and it does not "preempt or otherwise have any effect on" North Dakota's "laws regarding the prohibition of . . . coverage[] [or] funding . . . [of] abortions." 42 U.S.C. § 18023(c)(1).⁷ In light of these facts, Plaintiffs have failed to credibly explain how the Rule "pressures" them, Pls.' Br. 6, 7, much less requires them, to change their health care practices and health insurance policies concerning abortion.

Plaintiffs' arguments concerning insurance coverage for gender transition are also misguided. No Plaintiff has clearly alleged offering its employees health insurance with the kind

⁷ Even a cursory search reveals that North Dakota has laws that prevent state funds or facilities from being used for elective abortions—state laws that the Rule does not displace. 42 U.S.C. § 18023(c); *see, e.g.*, N.D. Cent. Code Ann. §§ 14-02.3-01, 14-02.3-04.

of categorical coverage exclusion or limitation for all services for gender transition that the Rule prohibits.⁸ Far from “real,” “substantial,” and “immediate,” *Lyons*, 461 U.S. at 111, the injuries that Plaintiffs allege are conjectural.

Plaintiffs also purport to identify the Rule’s effects by mischaracterizing parts of the Rule’s preamble as requirements. *E.g.*, Pls.’ Br. 7-11. At root, Plaintiffs’ error lies in viewing the Rule as imposing specific demands, when in fact it requires covered entities only to provide health care and health insurance in a nondiscriminatory manner. *See, e.g.*, 81 Fed. Reg. at 31,429, 31,455. The Department’s approach in the Rule embodies bedrock principles of antidiscrimination law. If, for example, a patient alleges that a provider treated him or her differently on a ground prohibited under the Rule, the provider can advance a legitimate, nondiscriminatory reason for the provider’s actions—*e.g.*, medical judgment—which will be considered, along with any statutory protections, before it is determined whether Section 1557 has been violated. *See generally McDonnell Douglas Corp. v. Green*, 411 U.S. 792, 802-03 (1973). Time and again in the rulemaking, therefore, in any number of different contexts, the Department emphasized that it will “evaluate[] each situation on a case-by-case basis.” 81 Fed. Reg. at 31,393; *accord id.* at 31,419, 31,432, 31,440; 80 Fed. Reg. at 54,185. In the face of these commitments, Plaintiffs’ alleged injuries can only be speculative.

⁸ *Cf.* Pls.’ Ex. A ¶ 13 (asserting that it would violate the Sacred Heart clinics’ “religious beliefs . . . if they were forced to offer a health plan that included benefits for . . . any drugs or procedures related to gender transition”); Pls.’ Ex. B ¶ 11 (same, SMP Health System); Pls.’ Ex. C ¶ 14 (same, University of Mary); Compl. ¶¶ 51-59 (stating no allegations with regard to any employee health benefit plans offered by Sisters of Mercy); *id.* ¶ 90 (stating only that SMP Health System’s “employee health benefits plans specifically exclude coverage for . . . [g]ender transition *surgeries* and treatment leading to and/or related to such *surgeries*” (emphasis added)); *id.* ¶ 103 (alleging that the University of Mary’s health plan excludes coverage for “[t]reatment leading to or in connection with sex change or transformation *surgery* and related complications” (emphasis added)); *id.* ¶¶ 117, 119 (stating certain allegations about the Rule’s purported effects on North Dakota’s employee health benefit plans but not clearly alleging that those plans include categorical exclusions for all gender transition procedures).

Finally, even if the Rule operated as Plaintiffs allege—which it does not—Plaintiffs’ claimed injuries still would be hypothetical. Plaintiffs have not identified any enforcement action against them under the Rule, whether by HHS or a private litigant, where a finding of unlawful discrimination and a termination of funding or a damages award are imminent. Even were such an action foreseeable, it could have no concrete effects until the conclusion of the extensive administrative and/or judicial procedures described above and addressed further below. Here, as in *Lyons*, “[t]he speculative nature of [Plaintiffs’] claim of future injury requires a finding that this prerequisite of equitable relief has not been fulfilled.” 461 U.S. at 111; *see, e.g., H&R Block Tax Servs., LLC v. Acevedo-Lopez*, 742 F.3d 1074, 1077 (8th Cir. 2014) (the “threat of irreparable injury” is “an *essential* part of [the] test” for deciding whether to issue a preliminary injunction).

II. PLAINTIFFS ARE UNLIKELY TO SUCCEED BECAUSE THE COURT LACKS JURISDICTION

Plaintiffs’ attempt to mount a pre-enforcement challenge to the Rule fails for several reasons: Plaintiffs’ claims are not ripe; Plaintiffs lack standing; and Section 1557 requires Plaintiffs to press their claims before HHS in any enforcement action that the Department might instigate to determine, in fact- and case-specific fashion, whether Plaintiffs have violated Section 1557, with judicial review then available thereafter.

A. Plaintiffs’ Claims Are Not Ripe And Plaintiffs Lack Standing

Because Plaintiffs’ alleged injuries are speculative and may never occur, their lawsuit is not ripe. The ripeness doctrine “prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and . . . protect[s] the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties.” *Ohio Forestry Ass’n, Inc. v. Sierra Club*, 523 U.S. 726, 732-33 (1998). Here, Plaintiffs’ overbroad and incorrect

assertions about what the Rule requires underscore the absence of a sufficiently concrete allegation of injury. Rather than challenging the application of the Rule in a particular instance, Plaintiffs seek to challenge aspects of the Rule in advance, and in the abstract. The ripeness requirement—which “safeguards against judicial review of hypothetical or speculative disagreements,” *Parrish v. Dayton*, 761 F.3d 873, 875 (8th Cir. 2014)—forecloses their attempt.

Plaintiffs’ speculation regarding the potential for a finding of unlawful discrimination by the Department and the loss of federal financial assistance “rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all.” *Texas v. United States*, 523 U.S. 296, 300 (1998).⁹ Plaintiffs’ concern about the possibility of private lawsuits against them under Section 1557 does not change the analysis. Were such lawsuits to be filed (and Plaintiffs have identified none pending against them), courts could judge at that point—on the basis of concrete facts, and after considering Plaintiffs’ defenses—whether any violation of Section 1557 had in fact occurred. At this stage, no case or controversy exists to justify this Court’s intervention.

Plaintiffs lack standing for similar reasons. The “irreducible constitutional minimum of standing” requires Plaintiffs to demonstrate, among other things, “injury in fact.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992). But the injuries Plaintiffs allege—a finding of unlawful discrimination and the prospective termination of federal financial assistance at the conclusion of administrative proceedings, damages liability at the conclusion of private lawsuits—are

⁹ Plaintiffs’ focus on examples and guidance provided in the Rule’s preamble is particularly misplaced. The D.C. Circuit rejected similar challenges as unripe in *Natural Resources Defense Council v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009). There, as here, the agency committed to “evaluat[ing] [matters] on a case-to-case basis,” such that the plaintiffs could “not demonstrate[] that any of the” examples given in the preamble “ha[d] immediate legal or practical consequences.” *Id.* Here, too, “[h]ow [the Department] will use or rely on or interpret what it said in the preamble is uncertain,” and there is no “significant hardship to the parties from waiting for a real case to emerge.” *Id.* That is especially true because Section 1557 “provides for judicial review of any [HHS] decision” to terminate federal financial assistance. *Id.*; see 42 U.S.C. § 2000d-2.

speculative. Their conjectural nature is confirmed by the fact that the Rule protects the nondiscriminatory expression and application of medical judgment; it incorporates federal statutory protections for religious freedom and conscience; it does not displace ACA provisions concerning abortion; and it does not require Plaintiffs to perform or cover any particular medical services but rather ensures that services are offered and covered in nondiscriminatory ways. Because Plaintiffs' alleged injuries are "conjectural" and "hypothetical," not "actual or imminent," Plaintiffs lack standing. *Spokeo, Inc. v. Robbins*, 136 S. Ct. 1540, 1548 (2016).

Delta Air Lines v. Export-Import Bank of the United States is instructive. 85 F. Supp. 3d 250 (D.D.C. 2015). At issue there were guidelines that the agency had adopted to help it decide, on a case-by-case basis, whether to approve or reject certain requests for financing. *Id.* at 255, 258. Rather than challenge the agency's application of the guidelines to a particular financing request, however, the plaintiffs brought a facial challenge before the guidelines had ever been applied. *Id.* at 258-59. Noting the Supreme Court's "'repeated[']" insistence "'that threatened injury must be *certainly impending* to constitute injury in fact, and that allegations of *possible* future injury are not sufficient,'" *id.* at 261 (quoting *Clapper v. Amnesty Int'l*, 133 S. Ct. 1138, 1147 (2013) (alterations omitted)), the court held that the plaintiffs lacked standing: they could not point to "any particularized and concrete . . . harms that have resulted or imminently will result from a specific financing commitment[,]. . . as no such commitments" were at issue, *id.* at 266. Plaintiffs lack standing here for the same reason: because they "challenge the [Rule] in the abstract, not in the context of a specific" enforcement action, their alleged injuries consist of "only hypothetical risks that may or may not materialize depending on when, how, and to whom the [Department] applie[s] [the Rule]" in the "future." *Id.*

The *Delta Airlines* court also held that the plaintiffs' claims were unripe, "find[ing] that further factual development [was] necessary" because it was "near impossible . . . to evaluate whether the [agency's] actions were consistent with [its enabling statute] in a factual vacuum, which is what occurs when the Court is asked to evaluate the facial validity of [the guidelines] outside the context of an actual financing decision." *Id.* at 270. Plaintiffs have asked this Court to undertake analogous, and similarly fraught, analyses. "Thus, in short, the Court . . . faces 'the classic institutional reason to postpone review: it [should] wait for [the Rule] to be applied [to Plaintiffs] to see what its effects will be.'" *Id.* at 271 (alterations omitted) (quoting *La. Envtl. Network v. Browner*, 87 F.3d 1379, 1385 (D.C. Cir. 1996)).

B. Section 1557 Requires Plaintiffs To Adhere To Its Specified Mechanisms For Administrative And Judicial Review

Plaintiffs' claims are not justiciable for another reason: Section 1557 evinces Congress's intent to prohibit pre-enforcement review by requiring exhaustion of administrative remedies and thereby delaying judicial review of Plaintiffs' claims. Any withdrawal of Plaintiffs' federal financial assistance by the Department could only occur after the comprehensive proceedings described above. 42 U.S.C. § 18116(a); *id.* § 2000d-1; *see* 45 C.F.R. §§ 92.301(a), 92.302. And Congress has ensured that any such determination would be subject to judicial review. 42 U.S.C. § 2000d-2. By imposing these requirements and assurances, Congress has divested this Court of jurisdiction over Plaintiffs' current (unexhausted) claims.

Congress commonly divests federal district courts of original federal question jurisdiction, *see* 28 U.S.C. § 1331, in two primary ways: "by imposing exhaustion requirements and by imposing channeling requirements," *Harkness v. United States*, 727 F.3d 465, 469 (6th Cir. 2013). With respect to exhaustion, the Supreme Court "has acknowledged the general rule that parties exhaust prescribed administrative remedies before seeking relief from the federal courts."

McCarthy v. Madigan, 503 U.S. 140, 144-45 (1992). “[E]xhaustion of administrative remedies is required where Congress imposes an exhaustion requirement by statute.” *Liadov v. Mukasey*, 518 F.3d 1003, 1006 (8th Cir. 2008) (quoting *Coit Independence Joint Venture v. FSLIC*, 489 U.S. 561, 579 (1989)). Channeling requirements are another way for Congress to “delay[] judicial review” by “allocat[ing] initial review to an administrative body,” *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 207 (1994)—*i.e.*, to “remove certain claims from the general jurisdiction of the federal courts in order to channel [those] claims into a system of statutory review,” *Elgin v. Dep’t of Treasury*, 132 S. Ct. 2126, 2141 (2012). Where Congress creates a “special statutory review scheme . . . it is ordinarily supposed that Congress intended that procedure to be the exclusive means of obtaining judicial review in those cases to which it applies.” *Jarkesy v. SEC*, 803 F.3d 9, 15 (D.C. Cir. 2015).

“In some cases, including this one, the distinction between” an exhaustion requirement and a channeling provision “is difficult to locate, and is perhaps even illusory,” because “the effect of a congressional command is the same—judicial review is precluded until the statutory conditions have been met.” *Harkness*, 727 F.3d at 469. As described above, Congress has provided for a comprehensive scheme of administrative and judicial review for alleged violations of Section 1557. But rather than raising their claims in the context of a specific enforcement action to challenge a particular allegation of unlawful discrimination, Plaintiffs have asked this Court for a blanket, pre-enforcement determination that their practices are not discriminatory. This they cannot do. Whether viewed as channeling disputes to the agency prior to allowing for judicial review, or as instituting an exhaustion requirement, the comprehensive scheme that must precede any decision by the Department to terminate federal financial assistance on the basis of a violation of Section 1557 precludes this Court from considering Plaintiffs’ pre-enforcement claims.

That Congress, in Section 1557, opted to incorporate the “enforcement mechanisms provided for and available under” Title VI and Title IX, for example, 42 U.S.C. § 18116(a), illustrates this point. Many courts have held that Title VI enacts “a comprehensive plan of enforcement” that divests district courts of jurisdiction over pre-enforcement challenges like Plaintiffs’. *Taylor v. Cohen*, 405 F.2d 277, 279 (4th Cir. 1968).¹⁰ And facing a recent challenge to a Department of Education interpretation of Title IX, the *Highland* court concluded that that statute’s comprehensive review scheme deprived the court of jurisdiction. *See* 2016 WL 5372349, at *6-9 (disagreeing with *Texas v. United States*, No. 7:16-cv-54, 2016 WL 4426495, at *10 (N.D. Tex. Aug. 21, 2016)). Courts have likewise ruled that exhaustion is a prerequisite for judicial review under provisions of other statutory schemes that are incorporated by Section 1557.¹¹

The policy justifications underlying both the exhaustion and the channeling doctrines apply with particular force in this case. *See, e.g., McCarthy*, 503 U.S. at 145; *Elgin*, 132 S. Ct. at 2140. The administrative process under Section 1557 is designed to allow the Department to make case-by-case determinations as to whether impermissible discrimination has occurred and, in so doing, to adequately assess the facts surrounding the particular discrimination claim. In that way, ascertaining whether a covered entity has engaged in unlawful discrimination is the quintessential “exercise of the agency’s discretionary power,” such that requiring Plaintiffs to proceed through the administrative review scheme is particularly important. *See McCarthy*, 503 U.S. at 145.

¹⁰ *See, e.g., Bakersfield City Sch. Dist. of Kern Cty. v. Boyer*, 610 F.2d 621, 624 (9th Cir. 1979) (“Comprehensive procedural requirements must be met before Federal financial assistance can be terminated for noncompliance [under Title VI.]”); *accord NAACP v. Wilmington Med. Ctr., Inc.*, 453 F. Supp. 330, 340 (D. Del. 1978); *Sch. Dist. of the City of Saginaw v. U.S. Dep’t of Health, Educ. & Welfare*, 431 F. Supp. 147, 152 (E.D. Mich. 1977).

¹¹ *E.g.*, 42 U.S.C. § 1395cc(h)(1)(A); *see, e.g., Trade Around World of PA v. Shalala*, 145 F. Supp. 2d 653, 657 (W.D. Pa. 2001); *see also Mich. Ass’n of Homes & Servs. for Aging, Inc. v. Shalala*, 127 F.3d 496, 497 (6th Cir. 1997).

Moreover, were an administrative action instituted against any Plaintiff, that Plaintiff could demonstrate that its practices are not discriminatory or that various statutory protections apply. Permitting any necessary review, investigation, and ensuing administrative proceedings to take their course before judicial review “recognizes the notion, grounded in deference to Congress’ delegation of authority to coordinate branches of Government, that agencies, not the courts, ought to have primary responsibility for the programs that Congress has charged them to administer,” and would allow the Department to “apply its special expertise.” *Id.*; *see also Elgin*, 132 S. Ct. at 2140 (delaying judicial review might have the benefit of “obviat[ing] the need” for court intervention). It is not surprising, therefore, that exhaustion requirements are common for discrimination claims. *See, e.g., Bailey v. U.S. Postal Serv.*, 208 F.3d 652, 654 (8th Cir. 2000). The Court should conclude that Congress imposed such a requirement here.

III. PLAINTIFFS ARE UNLIKELY TO SUCCEED ON THE MERITS

For all the reasons set forth above, Plaintiffs are unlikely to succeed because this Court lacks jurisdiction. But even if this Court had jurisdiction, and even if Plaintiffs had demonstrated irreparable harm, the Court still should not issue a preliminary injunction because Plaintiffs are not likely to succeed on the merits of their claims.

A. Plaintiffs’ Statutory Challenges To The Rule Are Not Likely To Succeed

1. The Rule’s interpretation of Section 1557’s prohibition of sex discrimination as encompassing discrimination based on gender identity should be upheld under *Chevron*

Section 1557 provides, in relevant part, that “[a]n individual shall not, on the ground prohibited under . . . [T]itle IX . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance.” 42 U.S.C. § 18116(a). The “ground prohibited under” Title IX, *id.*, refers to discrimination “on the basis of sex,” 20 U.S.C. § 1681(a). Because Plaintiffs challenge a

regulation's interpretation of an authorizing statute, the familiar two-step *Chevron* framework applies. *See Chevron U.S.A. v. Natural Res. Def. Council*, 467 U.S. 837, 842-43 (1984). At step one, the Court determines “whether Congress has directly spoken to the precise question at issue.” *Id.* at 842. If not, the Court proceeds to step two to determine whether the Rule “is based on a permissible construction of the statute.” *Id.* at 843. The Rule passes that test.

a. Plaintiffs’ narrow interpretation of discrimination on the basis of sex is not compelled by the statutory text

Defendants agree that the statutory text should be the Court’s starting point at *Chevron* step one. *See* Pls.’ Br. 13-14. But Section 1557 does not define discrimination “on the basis of sex,” and neither does Title IX. Nor does either statute address how to determine an individual’s sex in the event of a conflict between genetic or anatomical makeup and gender identity, or in the event that different indicators point in different directions. Relying on outdated case law, Plaintiffs insist that the term “sex” unambiguously refers only to the “physiological differences between males and females.” *See id.* at 12-13 (citing *Sommers v. Budget Mktg., Inc.*, 667 F.2d 748 (8th Cir. 1982)). Yet Plaintiffs ignore that the Eighth Circuit subsequently has recognized that, under Title VII, sex discrimination includes discrimination based on “[g]ender stereotyping,” *see Hunter v. United Parcel Serv., Inc.*, 697 F.3d 697, 702 (8th Cir. 2012) (citing *Price Waterhouse*, 490 U.S. at 251), and that an individual claiming discrimination “based on his non-conformity to gender stereotypes or his being perceived as transgendered” falls within “a protected class,” *id.* at 702-03.

Indeed, since the Supreme Court’s 1989 decision in *Price Waterhouse*, it is well-established that discrimination “because of . . . sex” is not limited to preferring males over females (or vice-versa), but includes differential treatment based on “sex-based considerations” including (but not limited to) sex stereotyping. 490 U.S. at 242. Plaintiffs’ suggestion that Title IX’s prohibition against discrimination “on the basis of sex” bars only discrimination based on

anatomical and biological considerations, Pls.’ Br. 14, is irreconcilable with the Supreme Court’s holding in *Price Waterhouse*. This is confirmed by the “weight of circuit authority” recognizing that “discrimination against transgender individuals constitutes discrimination ‘on the basis of sex’ in the context of . . . statutes,” like Title VII, that are “analogous” to Title IX. *G.G. v. Gloucester Cty. Sch. Bd.*, 822 F.3d 709, 727 (4th Cir.) (Davis, J., concurring) (citing *Glenn*, 663 F.3d at 1316-19; *Smith v. City of Salem*, 378 F.3d 566, 573-75 (6th Cir. 2004); *Rosa v. Park W. Bank & Trust Co.*, 214 F.3d 213, 215-16 (1st Cir. 2000); *Schwenk v. Hartford*, 204 F.3d 1187, 1201-02 (9th Cir. 2000)), *mandate recalled, stay granted*, 136 S. Ct. 2442 (2016), *cert. granted*, No. 16-273, 2016 WL 4565643 (Oct. 28, 2016).¹² Applying *Price Waterhouse*, these cases recognize that there is “a congruence between discriminating against transgender . . . individuals and discrimination on the basis of gender-based behavioral norms.” *Glenn*, 663 F.3d at 1316; *see Smith*, 378 F.3d at 575 (“[D]iscrimination against a plaintiff who is a transsexual—and therefore fails to act and/or identify with his or her gender—is no different from the discrimination directed against Ann Hopkins in *Price Waterhouse*.”). Likewise, in *Hunter*, while the Eighth Circuit affirmed the district court’s determination that the “transgendered or gender non-conforming” plaintiff had failed to put forward evidence sufficient to substantiate his claim of discrimination, the Court of

¹² The Supreme Court has granted certiorari in *Gloucester* on the question whether a Department of Education interpretation of its own regulation in the context of transgender individuals’ access to sex-segregated facilities under Title IX should be given effect with or without deference to the agency. 2016 WL 4565643. At present, district courts are split on this question, although in keeping with *Gloucester*’s conclusion that “on the basis of sex” is ambiguous as applied to transgender persons, 822 F.3d at 721-22, most recent decisions favor the federal government’s interpretation, *see, e.g., Carcaño v. McCrory*, No. 1:16-cv-236, 2016 WL 4508192, at *12-13 (M.D.N.C. Aug. 26, 2016); *Highland*, 2016 WL 5372349, at *13; *Students & Parents for Privacy v. U.S. Dep’t of Educ.*, No. 16-cv-4945, 2016 WL 6134121, at *19 (N.D. Ill. Oct. 18, 2016); *Whitaker v. Kenosha Unified Sch. Dist. No. 1*, No. 16-cv-943, 2016 WL 5239829, at * 3 (E.D. Wis. Sept. 22, 2016). *But see Texas*, 2016 WL 4426495, at *14.

Appeals—following *Price Waterhouse*—did not question that the plaintiff possessed a “protected status.” 697 F.3d at 704.

Ignoring these authorities, Plaintiffs erroneously rely on *Sommers* even though it was decided before, and is inconsistent with, *Price Waterhouse* and *Hunter*. Pls.’ Br. 12-13. District courts within this Circuit have recognized that “the ‘narrow view’ of the term ‘sex’ in Title VII” advanced in *Sommers* “‘has been eviscerated by *Price Waterhouse*.’” *Radtko v. Misc. Drivers & Helpers Union Local No. 638*, 867 F. Supp. 2d 1023, 1032 (D. Minn. 2012) (quoting *Smith*, 378 F.3d at 573); see *Rumble v. Fairview Health Servs.*, No. 14-cv-2037, 2015 WL 1197415, at *2 (D. Minn. Mar. 16, 2015) (“Plaintiff’s transgender status is necessarily part of his ‘sex’ or ‘gender’ identity.”). These courts have correctly understood that *Sommers* has been abrogated by intervening Supreme Court authority, and this Court should treat *Sommers* similarly. See, e.g., *Smith*, 378 F.3d at 573; *Schwenk*, 204 F.3d at 1201 (explaining that “[t]he initial judicial approach” in cases like *Sommers* was “overruled by the logic and language of *Price Waterhouse*”).

In addition to relying on outdated case law, Plaintiffs advance unpersuasive arguments. Plaintiffs urge that the statute’s “purpose” should be paramount, but then fail to address the statute at issue here—the Affordable Care Act—at all. See Pls.’ Br. 15-16 (discussing only whether the purpose of *Title IX* was to ensure equal opportunities in education for women). The purpose of the ACA and Section 1557 is “to expand access to [health] care and coverage and eliminate barriers to access.” 81 Fed. Reg. at 31,377. Plaintiffs ignore that purpose. By contrast, the Rule’s interpretation of sex discrimination is the interpretation that best takes that purpose into account.

Nor is it particularly relevant that the Congress that enacted Title VII in 1964 and Title IX in 1972 may not have had transgender individuals specifically in mind. See Pls.’ Br. 15-16. The Supreme Court has instructed that the meaning of Title VII (and, by extension, Title IX) should

not be limited to what was in the minds of the legislators who drafted those statutes decades ago. *See Oncale v. Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 79 (1998) (noting, in holding that Title VII’s prohibition of discrimination on the basis of sex applied to same-sex sexual harassment, that “statutory prohibitions often go beyond the principal evil to cover reasonably comparable evils, and it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed”). Finally, the other statutes to which Plaintiffs point—VAWA amendments and the Hate Crimes Act, *see* Pls.’ Br. 16—do not answer the question at hand. There is no evidence that Congress intended the inclusion of “gender identity” in those distinct laws to imply that discrimination based on gender identity falls outside the meaning of discrimination “on the basis of sex.” Nor can any inference of intent be drawn from the fact that Congress has not amended Title IX to explicitly proscribe discrimination on the basis of gender identity. Many inferences can be drawn from a failure to amend an existing statute, “including the inference that the existing legislation already incorporated the offered change.” *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990).

b. The Rule’s interpretation of Section 1557 is reasonable and entitled to deference

To the extent that Section 1557’s prohibition on sex discrimination is ambiguous, the Court must proceed to *Chevron*’s second step. *See City of Arlington v. FCC*, 133 S. Ct. 1863, 1868 (2013). At step two, the agency’s interpretation need not be the “only permissible” one, *Chem. Mfrs. Ass’n v. Nat. Res. Def. Council*, 470 U.S. 116, 125 (1985), or even “the best or most natural one,” *Pauley v. BethEnergy Mines, Inc.*, 501 U.S. 680, 702 (1991). Rather, the agency’s construction need only fall “within the bounds of reasonable interpretation.” *Your Home Visiting Nurse Servs., Inc. v. Shalala*, 525 U.S. 449, 453 (1999). Here, as Plaintiffs acknowledge by failing to make any arguments addressing *Chevron*’s second step, they cannot demonstrate that they are

likely to succeed on their claim because HHS has cogently explained the reasoning behind the Rule, and this explanation more than satisfies step two's reasonableness requirement.

Through a robust rulemaking process, HHS weighed the various competing interests at stake in implementing Section 1557. Throughout, HHS was cognizant that “[o]ne of the central aims of the ACA is to expand access to health care and health coverage for all individuals” and that “[e]qual access for all individuals without discrimination is essential to achieving this goal.” 80 Fed. Reg. at 54,194. The notice-and-comment process confirmed the prevalence of discrimination against transgender individuals in health care. For example, the Department received 303 comments from individuals in response to its Request for Information, 239 of which “were personal testimonies from transgender individuals describing their experiences of discrimination in the health care setting.” *Id.* at 54,172. And in a recent survey considered by the Department, a remarkable 70% of transgender or gender non-conforming patients reported experiencing some type of discrimination in accessing (or attempting to access) medical services.¹³

To address these issues, in the NPRM, the Department proposed to define discrimination “on the basis of sex” to include, among other things, “gender identity,” and sought comment to ensure that this interpretation would “reflect the current state of nondiscrimination law.” 80 Fed. Reg. at 54,177. After considering all comments and authorities, the Department determined in the

¹³ See HUMAN RIGHTS CAMPAIGN, HEALTHCARE EQUALITY INDEX 2014 at 4 (2014), <https://goo.gl/bXfxnb>; see also LAMBDA LEGAL, WHEN HEALTH CARE ISN'T CARING: TRANSGENDER AND GENDER-NONCONFORMING PEOPLE at 1-2 (2010), <https://goo.gl/Zba507> (reporting that 27% of transgender survey respondents reported being refused needed care; 21% reported being subjected to harsh or abusive language by health care providers; over 15% reported experiencing the refusal of providers to touch them, or the use of excessive precautions during treatment; 20% reported being blamed for the medical problem for which they sought care; and almost 8% reported being subjected to physically rough or abusive treatment by providers). These and other materials were considered by the Department during the rulemaking and will be included in the administrative record that Defendants will produce in this case at the appropriate time.

final Rule that “its inclusion of gender identity is well grounded in the law.” 81 Fed. Reg. at 31,388; *see id.* at 31,384-85 & nn.42-43, 31,388-89 & nn.63-67 (collecting authorities). “As the Supreme Court made clear in *Price Waterhouse v. Hopkins*, in prohibiting sex discrimination, Congress intended to strike at the entire spectrum of discrimination against men and women resulting from sex stereotypes.” *Id.* at 31,388 (citing 490 U.S. at 251). Consistent with these authorities, HHS confirmed that transgender individuals are entitled to access health care that is medically indicated for them, free from discrimination on the basis of sex-based characteristics.

The Department’s construction is reasonable. Gender dysphoria is a medical diagnosis given to individuals who experience an ongoing “marked difference between” their “expressed/experienced gender and the gender others would assign” them; to alleviate the psychological stress that this disconnect creates, transgender individuals often undertake some level of gender transition.¹⁴ Determinations about appropriate medical care surrounding gender transition—including not only surgical measures, but also counseling and hormone therapy, *see* 81 Fed. Reg. at 31,434—must be made by physicians and their patients on an individualized basis, *see* WPATH STANDARDS at 5, 8-9, 58, 97. The Rule protects these processes and ensures that they are not affected by unlawful discrimination.

At *Chevron*’s second step, agency interpretations “are given controlling weight, unless they are arbitrary, capricious or manifestly contrary to the statute.” 467 U.S. at 844. Here, the

¹⁴ American Psychiatric Association, *Gender Dysphoria*, at 1 (2013), <http://www.dsm5.org/documents/gender%20dysphoria%20fact%20sheet.pdf>. The clinical basis for gender transition and the protocol for transitioning are well-established. *See, e.g.*, WORLD PROFESSIONAL ASSOCIATION FOR TRANSGENDER HEALTH, STANDARDS OF CARE FOR THE HEALTH OF TRANSSEXUAL, TRANSGENDER, AND GENDER-NONCONFORMING PEOPLE (7th ed. 2012) (“WPATH STANDARDS”), <https://goo.gl/6D8X8d> (included as Pls.’ Ex. H); *NCD 140.3, Transsexual Surgery*, Docket No. A-13-87, 2014 WL 2558402 (HHS DAB May 30, 2014) (included as Pls.’ Ex. J).

Department relied on the Affordable Care Act’s text and purpose, and decisions by courts and other federal agencies, in settling on a construction of the statute that addresses significant concerns related to sex-based discrimination in health care. Plaintiffs are unlikely to succeed in arguing that Section 1557 forecloses HHS’s interpretation.

2. Plaintiffs’ remaining statutory claims are meritless

Plaintiffs are also unlikely to succeed on their claim that the Rule exceeds the Department’s statutory authority because it does not import certain exemptions Congress has provided under Title IX into the health care context. Pls.’ Br. 18-20. The Rule *does* incorporate “[f]ederal statutory protections for religious freedom and conscience,” 45 C.F.R. § 92.2(b)(2)—including the Weldon, Church, and Coats amendments, and RFRA—and does not “displace . . . provisions in the ACA related to abortion services,” that is, the specific exemptions in the statutory scheme at issue here, *see* 81 Fed. Reg. at 31,379 & n.14. While *Title IX* contains a religious exemption, *see* 20 U.S.C. § 1681(a)(3) (exempting an “educational institution which is controlled by a religious organization” under certain circumstances), and a provision ensuring “[n]eutrality with respect to abortion,” *see id.* § 1688, *Section 1557* does not, *see* 42 U.S.C. § 18116.

As the Department explained, “Title IX and its exemption are limited in scope to educational institutions, and there are significant differences between the educational and health care contexts that warrant different approaches.” *See* 81 Fed. Reg. at 31,380. “[S]tudents or parents selecting religious educational institutions typically do so as a matter of choice,” whereas “[i]n the health care context . . . individuals may have limited or no choice of providers, particularly in rural areas or where hospitals have merged with or are run by religious institutions.” *Id.* This difference becomes particularly acute when “emergency circumstances” are considered. *See id.* Exempting all religious health care providers from the Rule’s prohibition on sex discrimination “could result in a denial or delay in the provision of health care to individuals . . .

with serious and, in some cases, life threatening results.” *Id.* The Department therefore opted for a “more nuanced approach” that nevertheless respects providers’ religious and conscience-based objections and, among other things, expressly references the specific abortion-related provision in the Affordable Care Act, the statute in which Section 1557 is contained. *See id.* at 31,379-80 & nn.14, 17-18. Because the Department has “articulate[d] a rational connection between the facts found and the choice[s] made,” and because its decisionmaking “path may reasonably be discerned,” its choices must be upheld under the APA’s “narrow” standard of review. *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285-86 (1974).

Finally, as explained above, *see supra* Section I, and contrary to Plaintiffs’ claim, *see* Pls.’ Br. 20, the Rule does not prevent employers from providing their employees with reasonable religious accommodations. In addition, because the Rule expressly prohibits any application that would violate the Religious Freedom Restoration Act, *see* 45 C.F.R. § 92.2(b)(2); 81 Fed. Reg. at 31,379 & n.13, Plaintiffs’ pre-enforcement RFRA challenge to the Rule, Pls.’ Br. 21-29, necessarily cannot succeed.

B. Plaintiffs’ Constitutional Challenges Are Not Likely To Succeed

If the Court were to find Plaintiffs likely to succeed in arguing that Section 1557’s prohibition on sex discrimination does not encompass discrimination based on gender identity, there would be no basis for the Court to consider any of Plaintiffs’ constitutional claims. *See, e.g., Nw. Austin Mun. Util. Dist. No. One v. Holder*, 557 U.S. 193, 205 (2009) (“[I]t is a well-established principle governing the prudent exercise of this Court’s jurisdiction that normally the Court will not decide a constitutional question if there is some other ground upon which to dispose of the case.”). But if the Court does not agree with Plaintiffs’ *Chevron* arguments, Plaintiffs’ remaining claims fail for the reasons stated below.

1. The Rule Does Not Violate The Spending Clause

Plaintiffs contend that the Rule violates the Spending Clause, U.S. Const., art. I, § 8, cl. 1, either by failing to provide clear notice of the conditions on which federal funding was predicated, or by unconstitutionally coercing the states that receive federal funding. Pls.’ Br. 28-30. Neither contention is likely to succeed.

The Spending Clause vests Congress with the “authority to ‘attach conditions on the receipt of federal funds, and Congress has repeatedly employed the power to further broad policy objectives by conditioning receipt of federal money upon compliance by the recipient with federal statutory and administrative directives.’” *Van Wyhe v. Reisch*, 581 F.3d 639, 649 (8th Cir. 2009) (alterations omitted) (quoting *South Dakota v. Dole*, 483 U.S. 203, 206 (1987)). “Once Congress clearly signals its intent to attach federal conditions to Spending Clause legislation, it need not specifically identify and proscribe in advance every conceivable state action that would be improper.” *Benning v. Georgia*, 391 F.3d 1299, 1306 (11th Cir. 2004); *see Van Wyhe*, 581 F.3d at 650-51 (“setting forth every conceivable variation in the statute is neither feasible nor required” (citing, *inter alia*, *Benning*, 391 F.3d at 1306)). For example, in *Davis v. Monroe County Board of Education*, the Supreme Court held that Title IX’s prohibition on sex discrimination in schools provided adequate notice that severe student-on-student sexual harassment was actionable, even though “the level of actionable ‘harassment’ . . . ‘depends on a constellation of surrounding circumstances, expectations, and relationships.’” 526 U.S. 629, 651 (1999) (quoting *Oncale*, 523 U.S. at 82); *see also Jackson v. Birmingham Bd. of Educ.*, 544 U.S. 167, 1509 (2005) (noting that Title IX’s conditions have been “broadly” interpreted “to encompass diverse forms of intentional sex discrimination”). Here, the prohibition on sex discrimination in Section 1557 and the Rule is sufficiently “clear and actionable.” *Benning*, 391 F.3d at 1306.

Moreover, Plaintiffs are incorrect to suggest that 1965, when Medicaid and Medicare were adopted, is the relevant time period for assessing whether they were on notice about the scope of Section 1557's prohibition against sex discrimination. Pls.' Br. 29-30; *see, e.g., Dole*, 483 U.S. at 208 (finding clear statement doctrine satisfied based on the clarity of the Federal Highway Act as amended in 1984, not looking back to 1956 when the Act was adopted). In any event, when Section 1557 was enacted in 2010, *Price Waterhouse* and its progeny already had indicated that discrimination because of sex can include discrimination because of sex-based considerations, including the failure to adhere to sex stereotypes or the divergence between a person's gender identity and his or her birth-assigned sex.

Finally, Plaintiffs' coercion claim, *see* Pls.' Br. 30, also is not viable. The Supreme Court has explained "that in some circumstances the financial inducement offered by Congress might be so coercive as to pass the point at which pressure turns into compulsion." *Dole*, 483 U.S. at 211; *see also Nat'l Fed. of Indep. Bus. v. Sebelius* ("NFIB"), 132 S. Ct. 2566, 2606 (2012). *NFIB* held that coercion may occur when Congress leverages an old and large program to force states to participate in a new one. 132 S. Ct. at 2607 ("What Congress is not free to do is to penalize States that choose not to participate in [a] new program by taking away their existing . . . funding."). By contrast, the nondiscrimination condition set forth in Section 1557, and interpreted in the Rule, is not a "new program." Rather, as evidenced by Section 1557's explicit references to Title VI, Title IX, Section 504, and the Age Act, 42 U.S.C. § 18116(a), Section 1557 embodies the type of nondiscrimination condition on federal spending *for existing programs* that has existed for decades. *See, e.g., Van Whye*, 581 F.3d at 651-52 (surveying Eighth Circuit decisions rejecting

Spending Clause challenges to Section 504).¹⁵ No court has suggested that coercion might occur when the federal government requires states to refrain from discrimination in using federal funds. This Court should not be the first.

2. Plaintiffs Cannot Succeed On Their First Amendment Claim Because The Rule Does Not Compel Or Curtail Speech

Plaintiffs maintain that the Rule runs afoul of the First Amendment’s Free Speech Clause “by prohibiting doctors from expressing some points of view and compelling them to express others.” Pls.’ Br. 30. Not so. Although Plaintiffs are correct that “[t]he government may not prohibit the dissemination of ideas that it disfavors, nor compel the endorsement of ideas that it approves,” *Knox v. Serv. Employees Int’l Union, Local 1000*, 132 S. Ct. 2277, 2288 (2012), Plaintiffs’ claim fails for a simple reason: the Rule neither curtails nor compels any speech protected by the First Amendment. Plaintiffs’ theory to the contrary, *see* Pls.’ Br. 30-33, rests entirely on statements in the Rule’s preamble that they take out of context. The Department’s observations that an “across-the-board categorization” of “all transition-related treatment as cosmetic or experimental” is “outdated and not based on current standards of care,” 81 Fed. Reg. at 31,429; *see id.* at 31,435, were made in the context of discussing “health-related *insurance plans* or other health-related *coverage*,” *id.* at 31,429 (emphasis added), and “equal access to health [insurance] *coverage*,” *id.* at 31,435 (emphasis added). While the Rule prohibits covered entities

¹⁵ *NFIB* is distinguishable for another reason as well. In *NFIB*, the Supreme Court found the Affordable Care Act’s expansion of Medicaid to be an improper exercise of Congress’s Spending Clause power not only because it effectively created a whole new program, but also because if the states refused to join that new program, the statute threatened to take away *all* of the states’ Medicaid funding. *See* 132 S. Ct. at 2604-06. By contrast, any termination of federal financial assistance under Section 1557 “shall be limited to the particular political entity, or part thereof, or other recipient as to whom . . . a finding [of discrimination] has been made and, shall be limited in its effect to the particular program, or part thereof, in which such noncompliance has been so found.” *E.g.*, 42 U.S.C. § 2000d-1.

from categorically excluding or limiting insurance coverage for all health services related to gender transition, *see* 45 C.F.R. § 92.207(b)(4), it places no parallel (or even similar) restrictions on what medical advice physicians can provide.

Thus, notwithstanding Plaintiffs’ allegations, the Rule does not prevent providers from expressing their medical opinions and speaking for or against transition procedures, to patients or otherwise.¹⁶ Plaintiffs also assert that “the Rule mandates revisions to healthcare professionals’ written policies, requiring express affirmance that transition-related procedures will be provided” and that the Rule requires providers to use a patient’s preferred name and gender. Pls.’ Br. 31. But even assuming the Rule would have these effects, Plaintiffs’ free speech claim fails. The purportedly “compelled speech to which [Plaintiffs] point is plainly incidental to the [Rule’s] regulation of *conduct*”—its prohibition on discrimination—“and ‘it has never been deemed an abridgment of freedom of speech . . . to make a course of conduct illegal merely because the conduct was in part . . . carried out by means of language, either spoken, written, or printed.’” *Rumsfeld v. Forum for Academic & Inst. Rights, Inc.* (“*FAIR*”), 547 U.S. 47, 62 (2006) (emphasis added) (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949)). Notably, the example the *FAIR* Court provided also arose in the antidiscrimination context: “Congress . . . can prohibit employers from discriminating in hiring on the basis of race. The fact that this will require an employer to take down a sign reading ‘White Applicants Only’ hardly means that the law should be analyzed as one regulating the employer’s speech rather than conduct.” *Id.*

¹⁶ Of course, the Rule may prohibit discriminatory harassment that masquerades as the expression of medical judgment without violating the First Amendment. *See, e.g., Jenson v. Eveleth Taconite Co.*, 824 F. Supp. 847, 884 n.89 (D. Minn. 1993) (“Title VII may legitimately proscribe conduct, including undirected expressions of gender intolerance, which create an offensive working environment. That expression is ‘swept up’ in this proscription does not violate First Amendment principles.” (quoting *R.A.V. v. City of St. Paul*, 505 U.S. 377, 389 (1992))).

3. Plaintiffs Have Not Met Their Heavy Burden In Attempting A Facial, Pre-Enforcement Vagueness Challenge

Plaintiffs have failed to demonstrate a likelihood of success on the merits of their Fifth Amendment void-for-vagueness challenge as well. Plaintiffs face a “heavy burden” in seeking to demonstrate that the Rule is facially void for vagueness. *Farmers Union Agency, Inc. v. Butenhoff*, 808 F. Supp. 677, 683 (D. Minn. 1992); *see also Roark & Hardee LP v. City of Austin*, 522 F.3d 533, 547 (5th Cir. 2008) (“In the context of pre-enforcement review, . . . examining facial vagueness is often difficult, perhaps impossible, because facts are generally scarce.”). That is particularly so given that the Rule does not involve criminal consequences. *See United States v. Articles of Drug*, 825 F.2d 1238, 1244 (8th Cir. 1987).

Plaintiffs offer no grounds for the Court to conclude that the Rule is “so vague and indefinite as really to be no rule or standard at all.” *Boutilier v. INS*, 387 U.S. 118, 123 (1967). Plaintiffs base their claim of vagueness almost entirely on the preamble, *see* Pls.’ Br. 33-37, ignoring that the Rule itself speaks in concrete, digestible terms modeled precisely on those found in the longstanding civil rights statutes that Section 1557 cites. Plaintiffs highlight that, with respect to certain issues, HHS declined to provide examples of prohibited discrimination. *E.g., id.* at 36. Yet Plaintiffs cite no case supporting the proposition that nondiscrimination provisions must be accompanied by concrete examples, or that an agency declining an invitation to provide examples somehow itself renders a regulation unconstitutionally vague. Plaintiffs counter that the Rule leaves the agency with too much discretion, but “with pre-enforcement challenges, such as this, ‘the speculative danger of arbitrary enforcement does not render the ordinance void for vagueness.’” *Miata v. City of Daytona Beach*, No. 6:14-cv-1428, 2015 WL 506287, at *5 (M.D. Fla. Feb. 6, 2015) (quoting *Vill. of Hoffman Estates v. Flipside*, 455 U.S. 489, 503 (1982)). Nor can Plaintiffs succeed by coming up with hard cases or attempting to tease inconsistency from the

Rule. *See* Pls.’ Br. 35. “It will always be true that the fertile legal ‘imagination can conjure up hypothetical cases in which the meaning of (disputed) terms will be in . . . question,’” but more is required to render the Rule void for vagueness. *Farkas v. Miller*, 151 F.3d 900, 906 (8th Cir. 1998) (quoting *Grayned v. City of Rockford*, 408 U.S. 104, 112 n.15 (1972)).

IV. THE BALANCE OF THE EQUITIES AND THE PUBLIC INTEREST FAVOR DENYING PRELIMINARY INJUNCTIVE RELIEF

Even had Plaintiffs established irreparable injury, jurisdiction, and a likelihood of success on the merits, the Court should still deny their motion. Plaintiffs have not demonstrated that their alleged injuries outweigh the harm that an injunction would cause Defendants and unrepresented third parties, and that granting an injunction would serve the public interest.

Plaintiffs have not made any showing of injury here, let alone injury that is substantial, imminent, and irreparable. Against this non-showing weighs the significant public interest in achieving Section 1557’s goals of eliminating discrimination in health care. Courts presume that violations of federal civil rights statutes constitute irreparable harm.¹⁷ More generally, there is “inherent harm to an agency” in preventing it from enforcing statutes and regulations that “Congress found it in the public interest to direct that [it] develop and enforce.” *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008); *see Nken v. Holder*, 556 U.S. 418, 420 (2009) (harm to opposing party and public interest “merge when the Government is the opposing party”).¹⁸

¹⁷ *See Silver Sage Partners, Ltd. v. City of Desert Hot Springs*, 251 F.3d 814, 827 (9th Cir. 2001); *Roberts v. Colo. State Bd. of Agric.*, 998 F.2d 824, 833 (10th Cir. 1993); *Rogers v. Windmill Pointe Vill. Club Ass’n*, 967 F.2d 525, 528 (11th Cir. 1992) (per curiam); *United States v. Hayes Int’l Corp.*, 415 F.2d 1038, 1045 (5th Cir. 1969).

¹⁸ In this regard, while Plaintiffs are entitled to no relief for all the reasons explained above, if the Court disagrees, the Court can only preliminarily enjoin Defendants from enforcing the two aspects of the Rule that Plaintiffs challenge—its prohibition against discrimination on the bases of gender identity and termination of pregnancy—and only as to Plaintiffs. *See Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981) (a preliminary injunction’s “limited purpose” is “merely to preserve the relative positions of the parties until a trial on the merits can be held” (emphasis

Plaintiffs' delay in seeking relief further militates against granting their motion. The Rule was published on May 18, 2016, but Plaintiffs waited more than five months to file suit (on November 7) and another ten days before moving for a preliminary injunction (on November 17). “[F]ailure to act sooner undercuts the sense of urgency that ordinarily accompanies a motion for preliminary relief and suggests that there is, in fact, no irreparable injury.” *Avia Sports, Inc. v. Fingerhut Direct Mktg., Inc.*, No. 09-cv-1091, 2010 WL 2131007, at *1 (D. Minn. May 25, 2010) (quoting *Weight Watchers Int’l, Inc. v. Luigino’s, Inc.*, 423 F.3d 137, 144 (2d Cir. 2005)); see *Hubbard Feeds, Inc. v. Animal Feed Supplement, Inc.*, 182 F.3d 598, 603 (8th Cir. 1999). Not only are Plaintiffs’ assertions of irreparable injury speculative; they also have come too late.

CONCLUSION

Defendants respectfully request that the Court deny Plaintiffs’ motion.

Dated: December 7, 2016

Respectfully Submitted,

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney
General

JENNIFER D. RICKETTS
Director, Federal Programs Branch

SHEILA M. LIEBER
Deputy Director, Federal Programs Branch

/s/ Adam Grogg
ADAM GROGG
EMILY BROOKE NESTLER
BAILEY W. HEAPS
Trial Attorneys
United States Department of Justice

added)). The role of an injunction is not to “enjoin all possible breaches of the law,” but to “remedy the specific harms” allegedly suffered by the plaintiffs themselves. *Zepeda v. INS*, 753 F.2d 719, 728 n.1 (9th Cir. 1983) (quoting, *inter alia*, *Hartford-Empire Co. v. United States*, 323 U.S. 386, 410 (1945)). Here, there has been no showing that non-plaintiff relief is required to protect Plaintiffs’ own interests during the pendency of these proceedings.

Civil Division, Federal Programs Branch
20 Massachusetts Ave. NW
Washington, DC 20530
phone: (202) 514-2395
fax: (202) 616-8470
email: adam.a.grogg@usdoj.gov

Counsel for Defendants

CERTIFICATE OF SERVICE

I hereby certify that on December 7, 2016, I electronically filed a copy of the foregoing. Notice of this filing will be sent via email to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's CM/ECF System.

/s/ Adam Grogg
ADAM GROGG